

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of : Toyohiko TAKUSHIGE and Etsuro HOSHINO  
Serial. No. : 10/583,500  
Filing Date : 06/19/2006  
For : Bacterial Intraoral Disease Treatment Composition  
Examiner : Irina KOSINSKI  
Art Unit : 4131

Honorable Commissioner of Patents and Trademarks  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

**DECLARATION UNDER 37 CFR §1.132**

I, Toyohiko TAKUSHIGE, a citizen of Japan, do hereby declare the following:

1. I am one of the joint inventors in the above-identified pending United States patent application, and am familiar with the specification, claims, and file history thereof.

2. I graduated from the School of Dentistry, Tohoku University in March, 1972. I obtained my license to practice as a dentist in June, 1972.

I obtained the degree of Doctor of Medical Dentistry from Niigata University in October, 2004.

3. I became a research assistant in the School of Dentistry, Tohoku University in April, 1972, and have been a Professor in the Graduate School of Dentistry, Tohoku University, since April, 2005.

I opened a dental clinic in Sendai City in November, 1980, where I currently practice.

4. I have reviewed the Office Action dated March 18, 2010 issued for the above-referenced patent application, in which Claim 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vermeer (US Patent # 5624906).

5. With regard to the Declaration I prepared on November 6, 2009, I provide the following explanation.

In regard to Experiment 1, the ratio of "polyethylene glycol 4000: propylene glycol" in sample 4 was erroneously described, and "3: 1" is correctly "1: 3". Similar error also exists in Table 1 of the specification. These errors were made by my mistake, and the errors were not intentional. When comparing samples 3 and 4, the migration distances of red food coloring were approximately equal, although they have different contents of

PEG 4000. (In both cases, the red food coloring migrated to the tip of the root, and the difference in the migration distances merely results from different lengths of the root of teeth used). Furthermore, comparison of samples 2 and 4 proves that PEG 4000 is a required component in the base, whereas the actual amount of PEG 4000 used is not important. The amount of PEG 4000 is just a value predetermined appropriately by a practitioner in order to adjust the viscosity of the base as desired.

In addition, "two small pieces 53 (about 1.0 mm in diameter)" each have a weight of 0.015 g or 0.02 g, and contain 0.01 g of red food coloring and 0.005 g (samples 1, 2 and 6) or 0.01 g (samples 3 to 5) of a base. The base in samples 1, 2 and 6 is a liquid having extremely low viscosity, because it was difficult to insert an amount as large as 0.01 g into "cylindrical hole". Being able to insert such a large amount of the base into the affected portion is considered to be one of advantages of the present invention.

6. In regard to Experiment 2, "two small pieces 53 (about 1.0 mm in diameter)" each have a weight of 0.02 g, and contain 0.01 g of red food coloring and 0.01 g of a base. The base has a composition of PEG 400: PEG 4000: PG = 1:2:2 in sample 7, and PEG 400: PEG 600: PEG 4000: PG = 2:2:2:3 in sample 8.

The migration distance of red food coloring was 9.0 mm in sample 7, and 18.0 mm in sample 8. Therefore, the base including PEG 400, PEG 600, PEG 4000 and PG of the present invention possesses superior penetrability compared to the penetrability of the mixture in the absence of PEG 600. These results were rather unexpected in view of the poor penetrability exhibited by PEG 600 alone.

It should be noted that as teeth would never have a red color before adding red food coloring, it is not necessary to compare before and after adding red food coloring upon the measurement of the migration distance of red food coloring. Therefore, a photograph of the teeth was not taken in Experiment 2 before red food coloring was added.

Since PEG 400 has extremely low viscosity, the use of a base constituted with only PEG 400 is significantly inferior to the use of a base of the present invention. Since PEG 4000 has too high a viscosity, the use of a base constituted with only PEG 4000 is also significantly inferior to the use of a base of the present invention. Accordingly, the migration distance of red food coloring was not determined on the PEG 400 or PEG 4000 bases since they have poor efficacy.

7. I hereby declare that all statements made herein are to my own knowledge true and that all statements made on information and assumptions are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

05/19/2010  
Date

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